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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,256	04/08/2004	Robbert Benner	2183.03-6420US	1851

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EXAMINER	
KIM, YUNSOO	
ART UNIT	**PAPER NUMBER**
1644	

MAIL DATE	DELIVERY MODE
06/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/821,256	BENNER ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8 and 10-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-8,10-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/23/07 has been entered.

2. Claims 1, 3-8 and 10-14 are pending.

3. In light of Applicants' amendments to the claims, the following rejections remain.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 3-7 and 10-14 stand rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/72831 (IDS reference, of record) as evidenced by Merck Index (17th ed. 1999, p. 1145-1146, 1841-1848, 2539, 2550, of record), Dwinnell et al. (Atlas of Diseases of the Kidney, Ch. 12, 1999, of record), Agrawal et al. (American Family Physicians, 2000, vol. 61, p. 2077-2088, corresponding on-line version of p. 1-20, newly cited) and Medline Plus Article (p. 1-3, newly cited).

Applicants' arguments filed on 2/22/07 have been fully considered but they are not persuasive.

Applicants argue that the amendment to the claims obviates the rejection because the claim is currently directed to a method for treating acute renal failure which is novel and patentable. Applicants further argue that the '831 publication does not mention treating of acute renal failure.

The '831 publication teaches a method of treating septic shock, various renal diseases, autoimmune diseases and chronic inflammatory diseases by administration of synthetic immunoregulator AQGV in a patient (p 3-4, 18,19, 22, 27, 44, 55, 61, claims 3, 13, 22-25, in particular). The '831 publication further teaches the administration of the immunoregulator intraperitoneally in PBS (p. 39, in particular).

As is evidenced in Merck Index, p. 1145-46, septic shock causes acute renal failure and the blood urea concentration is increased as result of renal failure. Furthermore, the Merck Index teaches major causes for acute renal failure being septic shock (p. 1842, table, in particular), patient with oliguria has increased blood urea nitrogen in serum (p. 1145, 1847, table, in particular), decreased secretion of urine compared to 1-2.4L/day comparable to less than 0.5ml/kg/hr (p. 1145, 1842, in particular), increased potassium (p. 2539, in normal being 3.5 -5.3mmol/L) and maintain at 6 mmol/L (p. 1845, in particular) as indication, symptoms and signs of renal failure.

As it is well known in the art and is further evidenced by the Dwinnell reference, the acute renal failure is defined as " abrupt deterioration of renal function sufficient to result in failure of urinary elimination of nitrogenous waste products (urea nitrogen and creatine), (p. 12.1, in particular). Dwinnell et al. further teaches that the deterioration of renal function results in elevation of blood urea nitrogen and serum creatine concentrations (p. 12.1, in particular). Moreover, Dwinnell particularly teaches that the dialysis, a well known therapeutic method for kidney diseases, provides removing of BUN (p. 12.3, Figure 12-4, in particular).

Moreover, as is evidenced by Agrawal et al. (p. 3, figure 1, in particular) and MedlinePlus Article (p. 1-3, in particular), the cause of acute renal failure is autoimmune diseases including inflammatory diseases and the autoimmune disorders including inflammatory diseases and the acute renal failure share many symptoms and therapeutic drugs (cyclophophamide and corticosteroids).

Thus, treating acute renal failure with the composition comprising oligopeptide consisting of SEQ ID NO:2 which is useful to treat autoimmune disorders and chronic inflammatory diseases is the inherent property of the composition comprising oligopeptide consisting of SEQ ID NO:2. In light of discussion above, the reference teachings anticipate the claimed invention.

6. Claims 1, 3-5, 7, 8 and 10-14 stand rejected under 35 U.S.C. 102(e) as being anticipated by 2004/0013661 (IDS reference, of record) as evidenced by Merck Index (17th ed. 1999, p. 1145-1146, 1841-1848, 2539, 2550, of record), Merriam Webster's Dictionary (p. 82, of record), Dwinnell et al. (Atlas of Diseases of the Kidney, Ch. 12, 1999, of record), Agrawal et al. (American Family Physicians, 2000, vol. 61, p. 2077-2088, corresponding on-line version of p. 1-20, newly cited) and Medline Plus Article (p. 1-3, newly cited).

Applicants' arguments filed on 2/22/07 have been fully considered but they are not persuasive.

Applicants argue that the amendment to the claims obviates the rejection because the claim is currently directed to a method for treating acute renal failure which is novel and patentable. Applicants further argue that it is impossible that the experiments in the '661 publication inherently reduce BUN concentration and treats acute renal failure.

The '661 publication teaches a method of treating inflammatory diseases, septic shock and ischemia reperfusion injury by administration of pharmaceutical composition comprising synthetic immunoregulator AQGV in bolus (e.g. orally) or infusion (parenterally) with dose of 1-5 mg/kg bodyweight (abstract, claim 1, [0021-23], [0043-45], [0050], in particular).

The '661 publication further teaches use of combination of immunoregulator ([0048]) and the use of diagnostic process to determine disease stage (claim 1).

As is evidenced in Merck Index, p. 1145-46, septic shock causes acute renal failure and the blood urea concentration is increased as result of renal failure. Furthermore, the Merck Index teaches major causes for acute renal failure being septic shock (p. 1842, table, in particular), patient with oliguria has increased blood urea nitrogen in serum (p. 1145, 1847, table, in particular), decreased secretion of urine compared to 1-2.4L/day comparable to less than 0.5ml/kg/hr (p. 1145, 1842, in particular), increased potassium (p.

2539, in normal being 3.5 -5.3mmol/L) and maintain at 6 mmol/L (p. 1845, in particular) as indication, symptoms and signs of renal failure.

As it is well known in the art and is further evidenced by the Dwinnell reference, the acute renal failure is defined as " abrupt deterioration of renal function sufficient to result in failure of urinary elimination of nitrogenous waste products (urea nitrogen and creatine), (p. 12.1, in particular). Dwinnell et al. further teaches that the deterioration of renal function results in elevation of blood urea nitrogen and serum creatine concentrations (p. 12.1, in particular). Moreover, Dwinnell particularly teaches that the dialysis, a well known therapeutic method for kidney diseases, provides removing of BUN (p. 12.3, Figure 12-4, in particular).

Moreover, as is evidenced by Agrawal et al. (p. 3, figure 1, in particular) and MedlinePlus Article (p. 1-3, in particular), the cause of acute renal failure is autoimmune diseases including inflammatory diseases and the autoimmune disorders including inflammatory diseases and the acute renal failure share many symptoms and therapeutic drugs (cyclophophamide and corticosteroids).

Thus, treating acute renal failure with the composition comprising oligopeptide consisting of SEQ ID NO:2 which is useful to treat autoimmune disorders and chronic inflammatory diseases is the inherent property of the composition comprising oligopeptide consisting of SEQ ID NO:2. In light of discussion above, the reference teachings anticipate the claimed invention.

7. The following new grounds of rejections are necessitated by the Applicants' amendment filed 2/22/07.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out this invention.

9. Claims 1, 3-8 and 10-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The specification and the original claims as filed do not provide a written description for the phrase "treating acute renal failure". The original claim 2 provides the written support for the subject is "**undergoing** acute renal failure" and the original claim 1 was drawn to a reducing the blood urea nitrogen concentration in a subject. The method of treating acute renal failure affects conditions other than reducing blood urea nitrogen concentration such as extracellular fluid volume loss of sequestration of kidney, creatine level or calcium level in blood.

10. No claim is allowable.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on M-F,9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim
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June 7, 2007

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